Plaintiffs' Memorandum in Opposition to Joint Motion for Summary Judgment for Failure to Prove Fault Element of Public Nuisance Claims

Ex 23 – CAH_MDL2804_03309960-971

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January 23, 2008
Via E-Mail:
Jodi.Avergun@cwt.com

Jodi Avergun
Special Counsel
Cadwalader, Wickersham & Taft, LLP
1201 F. Street, N.W.
Washington, DC 20004

Dear Ms. Avergun:

I have attached for your information and review our initial findings and recommendations on Cardinal Healthcare's Suspicious Order Monitoring (SOM) System.

From our initial review, it does not appear that implementation of Cardinal's Phase I SOM system procedures will meet the regulatory requirements without additional real-time monitoring capabilities (though we understand Phase II is under development and will address a number of these issues). As you will note from the report, the Drug Enforcement Administration's (DEA) communication to registrants on December 27, 2007, will require that registrants develop more controls than are plainly visible from a reading of the regulations. Additionally, the DEA has offered no guidance in terms of the minimum acceptable system requirements. In light of these new developments, work will continue with Cardinal to develop a computer system that is compliant with defensible statistical procedures and to further develop rigorous procedural tests to ensure that the program does not rely on the computer system alone.

Please advise if you require additional information and/or further clarification.

Sincerely,

Ronald W. Buzzeo

Ronald W. Buzzeo
Chief Regulatory Officer

RWB:adm
Attachment: Cardinal Healthcare's Suspicious Order Monitoring (SOM) System–Phase I

ATTORNEY CLIENT PRIVILEGED/CONFIDENTIAL

Cardinal Healthcare's Suspicious Order Monitoring (SOM) System – Phase I

Executive Summary:

From approximately December 6, 2007 through the present, Cegedim Dendrite staff, including Chief Regulatory Officer Ronald W. Buzzeo, R.Ph., have been working with Cardinal Healthcare's (Cardinal) executive management on numerous regulatory issues, including suspicious order monitoring (SOM), training, on-site interviews of staff and investigations related to new and existing customers.

Information pertaining to Cardinal's SOM system has been gathered during on site visits at Cardinal's headquarters and follow up conference calls and email correspondences with a number of Cardinal employees including Mr. Michael Mone, Vice President for Anti Diversion, Stephen J. Reardon, Vice President, Quality and Regulatory Assurance, and others. (Attachment 1 to this document is an email correspondence chain that includes a series of questions and answers between Mr. Mone and Mr. Buzzeo regarding the SOM system.) During the on site interview process, Mr. Reardon provided information to Cegedim Dendrite consultants Robert C. Williamson and William J. Reinig. Cegedim Dendrite IT Specialists Sharon Dennis, Scott Hardy, and Barbara Hess also made on site visits to evaluate the Phase I SOM system from an IT standpoint and to prepare for the execution of a validation exercise for Cardinal's SOM system.

According to Mr. Reardon, Cardinal's suspicious order monitoring system is modeled after the system designed by AmerisourceBergen (Amerisource) and this system relies upon groupings of drugs and groupings of customers. The average order quantity of each group of drugs is calculated on a monthly basis for each customer group. Orders that are three times the monthly average are blocked and investigated. According to Mr. Reardon, in the Amerisource system, Schedule III, IV and V controlled substances that are eight times the monthly average are blocked.

However, issues continue to emerge which will have to be resolved before the system will be in compliance with the regulations (21 CFR 1301.74(b)) and the Drug Enforcement Administration's (DEA's) guidance, as reflected in the letters the DEA forwarded to the industry in September, 2006, February, 2007 and December, 2007.

Cegedim Dendrite staff reviewed the Phase I deployment of Cardinal's SOM program and the findings herein are limited to the Phase I system. (Phase II development and testing is in process.) Phase I includes only four controlled substances and is applicable to only certain customer accounts. An additional regulatory deficiency associated with the Phase I system is that an order that is "blocked" as being possibly suspicious is simply reduced to the threshold limit and filled. These and other deficiencies must be eliminated immediately and corrective measures should be included in Phase II when launched. Upon review and audit of the system followed by computer systems validation testing, a determination will be made if the methodologies are sufficient.

An additional concern with the Phase I system relates to the ability of the system to track deviations in individual ordering patterns. This requirement is specifically addressed in the regulation. This was brought to the attention of Mr. Reardon during an on site interview on December 21st and he indicated that Cardinal could discern this information from the "ingredient limit report" (and thus this requirement was not further incorporated in the SOM system). Cardinal's "ingredient limit reports" are based upon historical information and are not sufficient to monitor deviations in ordering patterns on a real time basis. We believe real time analysis is required.

A communication received by Cardinal and other DEA registrants dated December 27, 2007, has further complicated Cardinal's ability to implement a fully compliant suspicious order monitoring program. This communication has advised registrants that the DEA does not "approve" SOM systems and establishes additional concerns for registrants who are revising their suspicious order monitoring systems.

Additional findings and recommendations are contained in the report.

Findings and Recommendations:

1. **Cardinal's Phase I Suspicious Order Monitoring System is incomplete and does not meet the regulatory requirements. (However, because Phase II is scheduled to be implemented by February 2008, it is clear that this interim system was intended to only be an initial first step at implementation.)**

Mr. Reardon indicated that Cardinal was planning to launch the SOM system in two phases. In Phase I only four controlled substances would be included (hydrocodones, oxycodones, phentermine and alprazolam). According to Mr. Reardon, these were the drugs that had been highlighted during the DEA's investigation of the Houston distribution center. Cardinal intended to organize their controlled substances by the drug codes contained in the Code of Federal Regulations. Packaging sizes would be normalized to "dosage units." Only solid dosage units would be included in Phase I. Customers would be grouped into like groups; however, not all customer groupings would be evaluated in the initial phase.

The basic process is to establish monthly averages for each drug for each group. Our understanding from Mr. Reardon is that the monthly averages are established by Cardinal's QRA department. Customer orders that are in excess of three times the average (which would be the threshold) would be held for further investigation. Orders that were held would be reduced to the threshold and sent to the customer. Delayed orders would be investigated. If the order was cleared of suspicion, the remainder of the order would be furnished to the customer. If the order was not cleared of the suspicion, the order would not be filled above the threshold limit; however, no report would be made to the DEA. Cegedim Dendrite views average settings as a comparison tool, but not in itself sufficient to be in full compliance with the regulations.

Only independent retail pharmacies would be investigated during Phase I. Individual customer groupings were to be further subdivided into small, medium and large to eliminate the possibility that large pharmacies would be blocked only because they routinely order large amounts of drugs, including controlled substances. Customers would be classified as small, medium and large based the total dollar volume of prescription business during a measured period.

Recommendations[1]

a. Expand the system to include all controlled substances and List I chemicals.

b. Expand the system to include all DEA registrants, such as pharmacies and other accounts, including government accounts, managed care, physicians, hospitals, manufacturers / repackagers, contract distributors, etc.

[1] We understand from informal consultations that recommendations a, b, c, d, and e are already accepted and planned as a part of the Phase II SOM.

c. Expand the system to include all dosage units.

d. Review all orders in their entirety and in real time.

e. Report all orders to the DEA that cannot be cleared of suspicion and cancel the entire order.

2. Cardinal's Phase I Suspicious Order Monitoring System is not sufficient to comply with the language in the Code of Federal Regulations.

21 CFR 1301.74(b) specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern and orders of an unusual frequency. DEA's correspondence of December 27, 2007 indicates that, "These criteria are disjunctive and are not all inclusive."

Cardinal staff report that information regarding size and pattern can be gleaned from the "ingredient limit reports" that were previously submitted to the DEA on a monthly basis. However, it should be noted that these reports are historical. DEA's correspondence of December 27, 2007 states that "… registrants must conduct an independent analysis of suspicious orders *prior to completing a sale* to determine whether the controlled substances are likely to be diverted from legitimate channels" (emphasis added). This guidance is amplified in the same correspondence. The DEA states that "registrants that routinely report suspicious orders, yet fill these orders without first determining that order is not being diverted into other than legitimate medical, scientific and industrial channels, may be failing to maintain effective controls against diversion." Accordingly, an SOM system must be able to analyze, on a real time basis, pattern and frequency. Historical "ingredient limit reports," while useful, do not substitute for real time automated analysis of pattern and frequency.

Recommendations

a. Immediately commence development of a real time computer program that identifies orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency, even if the order is below the established threshold and/or standard deviation.

b. Review and block all orders in real time, perform an appropriate investigation, and report orders that cannot be cleared of suspicion to the DEA in a standard format by a single point of contact.

c. The entire order that cannot be cleared from suspicion should be cancelled and reported to the DEA and the account should be examined.

d. Ensure that thresholds and standard deviations/factors are only utilized as one part of an anti-diversion program

3. Cardinal's Phase I system may not meet statutory requirements.

It has been reported to us by Mr. Reardon, that Cardinal's system is based upon the Amerisource SOM system. In the fall of 2007, the DEA invited Amerisource to a DEA-sponsored industry conference (13th Pharmaceutical Conference, September 11 – 12, 2007, Houston, TX) to make a presentation regarding its SOM system. This resulted in the impression among Cardinal attendees and others that the Amerisource SOM system had the *imprimatur* of the DEA.

Mr. Reardon indicated that he attended this conference and that Michael Mapes, Chief, DEA, Regulatory Section, and Chris Zimmerman, Vice President, Corporate Security and Regulatory Affairs, Amerisource either indicated directly or implied that the Amerisource model could be considered a standard for SOM system development. Based on this impression, Mr. Reardon recommended the Cardinal SOM system be developed with functionality similar to the Amerisource methodology.

The Amerisource system apparently follows a methodology that was developed by the DEA's Suspicious Orders Task Force. This methodology is published on the DEA's web site.[2] This, of course, cannot be confirmed since a review of Amerisource's system has not been conducted. However, the Amerisource system (and Cardinal's system in development) is quite similar to the guidance published on the DEA's web site, and Cegedim Dendrite agrees that Cardinal's Phase I system comports with several indicia discussed in DEA's Chemical Handler's Manual. It should be noted that the chemical handler's manual is slightly dated, having been published in January 2004.

Regardless of Cardinal's prior impressions, in its December 27, 2007 communication to DEA registrants, the DEA has now stated that "past communications with DEA, whether implicit or explicit, that could be construed as approval of a particular system for reporting suspicious orders, should no longer be taken to mean that DEA approves a specific system."

This means that Cardinal's SOM system will have to rely on internal logistical strengths and performance measurements.

Recommendations

a. Subject all system methodologies to rigorous statistical analysis to assure that the system is statistically sound.

b. Proceed with plans to utilize an independent third party (Cegedim Dendrite) to execute "verification events" (or audits) to assure that the *SOM system* adequately identifies suspicious orders and that the orders are reported to the DEA.

[2] See deadiversion@usdoj.gov/publications/manuals/chemical handlers manual/appendices/Appendix E3

- Place test orders that are numerically small; however they would deviate from normal ordering patterns
- Place test orders that are of an unusual size and orders of an unusual frequency.
- Place test orders that are for highly abused controlled substances.
- Place test orders that are suspicious although they do not rely on the formula established through the data processing system (i.e., small but persistent orders for steroids in a location where an athletic team trains).

c. Proceed with plans to utilize an independent third party (Cegedim Dendrite) to perform a *computer systems* validation of the final configured system (and if determined appropriate, interim releases as well) to ensure accuracy, reliability, consistent intended performance, and regulatory suitability of the system.

Qualifications

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives could result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the DEA regulations and our experience with them. Many of the requirements of the DEA and regulations there under are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that DEA would not find any violations; the recommendations must be considered with this in mind.

3. No analysis has been provided as to the consequences of current or prior violations of DEA regulations, if any, which may be noted in this report.

Attachment 1: Email correspondences between Mr. Michael Mone and Mr. Ron Buzzeo

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From: Buzzeo, Ron
Sent: Tue 1/8/2008 4:44 PM
To: Avergun, Jodi; Mone, Michael; jcarney@bakerlaw.com
Cc: Hamby, Paul
Subject: RE: SOM

Michael

As a follow-up to our previous discussion on Cardinal's SOM system, I am confirming the list of questions that we discussed:

1. Number of retail and chains in the threshold categories for each controlled substance i.e. utilizing oxy as an example

	Retail	Chain
0 to 8000	____	____
8000 to 23,000	____	_____
23,000 to 45,000	_____	_____
45,000 to 70,000	_____	_____

2. If the controlled substance quantities from the targeted pharmacies were deleted would the thresholds decrease?

3. For controlled substances - does the SOM system have the capability of checking orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency even if below the threshold (monitoring from the initial order)?

4. Does the Cardinal SOM system go beyond the ASB system?

5. If we were to change from dollars to dosage units would there be an impact on determining small, medium and large?

6. If we only used controlled substances in our determination would there be an impact on determining small. medium and large?

Thank you

Ron

Ronald W. Buzzeo, RPh / Chief Regulatory Officer / Compliance Solutions Powered by BuzzeoPDMA / Cegedim Dendrite / Richmond, VA, 23225
Tel: 804-230-5002 / Fax: 804-267-1746 / Cell: 804-363-2071 / email: Ron.Buzzeo@dendrite.com

From: Mone, Michael [mailto:Michael.Mone@cardinalhealth.com]
Sent: Mon 1/14/2008 7:35 PM
To: Avergun, Jodi
Cc: Buzzeo, Ron
Subject: Answers

Jodi and Ron:

Here are the responses to the questions you have posed

Michael

Michael A. Moné, BS, JD, FAPhA
VP Anti-Diversion & Sr. Regulatory Counsel
Cardinal Health
7000 Cardinal Place
Dublin OH 43017
614-757-5104 [voice]
614-757-5826 [fax]

1. Number of retail and chains in the threshold categories for each controlled substance i.e. utilizing oxy as an example

Currently, Phase 1 of Cardinal Health's SOM only applies to Retail Independent customers. Cardinal's SOM will include all additional customers, including Chain Pharmacies, once Phase 2 is implemented in the beginning of February 2008. To establish initial threshold categories, all Retail Independent customers were classified as Small, Medium, or Large based on total Rx sales. An analysis was conducted of the customers that have been classified and uploaded as part of the current SOM program. Overall, 1,741 customers were classified as Large, while 1,806 and 3,237 customers were classified as Medium and Small respectively.

Pre-established limits were applied for all Retail Independent customers based on their size classification for each of the four drugs included of Phase 1 of the SOM program. The limits for an individual customer can be raised or lowered after an assessment by the QRA department. The tables below outline the number of customers classified within each limit for each drug. It should be noted that all tables below are based on limits assigned on January 1, 2008.

Oxycodone	
9,000	3,234
11,000	1,807
15,000	4
23,000	1,726
Above 23,000	13
Totals	**6,784**
Hydrocodone	
9,000	3,236
18,000	1,807
33,000	1,733
Above 33,000	8
Totals	**6,784**

Alprazolam	
5,300	3,236
7,000	1,806
13,000	1,736
Above 13,000	6
Totals	**6,784**

Phentermine	
1,200	3,236
1,400	1,807
1,700	1,741
Above 1,700	0
Totals	**6,784**

2. If the controlled substance quantities from the targeted pharmacies were deleted would the thresholds decrease?

When formulating the ranges for Small, Medium, and Large classifications, all pharmacies where controlled substance sales had been discontinued as a result of a QRA decision were excluded from the analysis. Therefore, it would not change the current thresholds. Additionally, the current thresholds are established based on total Rx sales for a six month period, not controlled substance quantities or dosage unit purchases.

3. For controlled substances - does the SOM system have the capability of checking orders of unusual size, orders deviating substantially from a normal pattern and orders of unusual frequency even if below the threshold (monitoring from the initial order)?

The current SOM system identifies orders that exceed the threshold limit that has been established for each customer. The program maintains a running count of the number of dosage units purchased by a customer each month. If a customer attempts to purchase more than the threshold limit, the order is cut and is not shipped. As part of the Anti-Diversion program going forward, analysis will be conducted to identify orders that deviate substantially from the customer's normal purchase pattern. This reporting and analysis will be retrospective and will not be conducted in real-time as the current SOM has been established. It is contemplated in a future enhancement if feasible that accounts will be identified by a different report where the weekly purchase aggregate by the customer exceeds a percentage threshold of then existing patterns of purchases [designed to capture spikes within a threshold limitation].

4. Does the Cardinal SOM system go beyond the ASB system?

Cardinal's SOM program, based on available information, meets or exceeds the ASB system.

5. If we were to change from dollars to dosage units would there be an impact on determining small, medium and large?

Yes, there would be a significant impact. Utilizing dosage units would potentially allow "risk" customers to order, and receive, more controlled substances. For example, a "risk" customer would be one that exclusively orders hydrocodone and has controlled substance account for 100% of its overall purchases. Since dosage units of hydrocodone are relatively inexpensive, this customer, basing size classification on dollars, would more than likely be classified as "Small." If we used dosage units, the customer would more than likely be identified as a "Large" customer due to their high orders of hydrocodone. Ultimately, Cardinal could be providing more hydrocodone to a customer who exhibits indicators of diversion (i.e. large % of controlled substance purchases and uneven product mix).

6. If we only used controlled substances in our determination would there be an impact on determining small. medium and large?

Yes, there would be an impact. As in the previous example, if only controlled substance sales were used, then the potential exists to provide higher limits to "risk" customers. If a customer has high controlled substances purchases, and no other purchases, the customer could be classified as Large and be given a higher limit. The result would be contrary to the purpose of the program by enabling potential diversion in larger quantities as a result of the classification. Additionally, the December 27, 2007 letter of the Drug Enforcement Administration clearly contemplates an action by a wholesaler to use the purchase of controlled substances in the absence of other prescription drugs and products as a factor in consideration of whether such a customer is potentially engaged in unlawful drug diversion.